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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,340	08/31/2006	Kai Rossen	7601/88254	9531
66991 7590 02/18/2010 LAW OFFICE OF MICHAEL A. SANZO, LLC 15400 CALHOUN DR. SUITE 125 ROCKVILLE, MD 20855				
EXAMINER LOEWEE, SUN JAE Y				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
02/18/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/591,340

Applicant(s)

ROSSEN ET AL.

Examiner

SUN JAE Y. LOEWE

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendments to the claims filed on October 22, 2009 have been fully considered. The arguments/amendments are not persuasive in overcoming the 35 USC 103 rejection. Below are responses to Applicant's further remarks.

Why would the combined references suggest crystallizing ketoprofines to stabilize them when none of the references include a crystallization step? Why would combining references that stabilize products by separation in a two phase system with a reference that does not stabilize products at all suggest using a one phase system in which products are stabilized by crystallization occurring concurrently with the addition of oxidizing agent? In the absence of an explanation as to how one gets from the cited references to the claimed invention, Applicants submit that the present rejection cannot be validly maintained.

The fact that a purification procedure (e.g., chromatography, ion exchange, etc.) is commonly used does not mean that its application to a particular problem involving compound stability is obvious. None of the references cited by the Examiner suggests stabilizing compounds by crystallization during oxidation reactions. Applicants also do not believe that crystallization according to the claimed process can reasonably be inferred based upon Riley teaching a one phase oxidation system and Narukawa teaching poor ketoproline solubility in aqueous solvents. These references are discussed further below.

Applicant's response is noted. One of ordinary skill would have the suggestion to practice the oxidation reaction of hydroxyproline in a single solvent which includes water. This suggestion is based on the reference of Riley. The goal of stabilization as a purpose for modifying the solvent system does not impart patentability, as the prior art would have suggested this modification. It is not necessary for the prior art to contemplate the correct purpose for this modification in order to suggest it.

However, even accepting that one of skill in the art would know that ketoproline is not very soluble in aqueous solvents, this does not make the use of crystallization during the addition of oxidizing agent to stabilize compounds in a one phase system obvious. Narukawa appears to have deliberately kept the ketoproline in solution; it does not report performing a crystallization as either a purification or stabilization step. This is also true of all of the other references cited.

One of ordinary skill is motivated to crystallize a product from solution as a form of purification. That the reference of Narukawa does not explicitly teach crystallization does not add patentability to the instant process.

In previous prosecution, Applicants have argued that it is not just the crystallization of ketoproline product that is important to the claimed invention but also the timing of the crystallization. The compounds must be crystallized rapidly after they are made in order to prevent further oxidation steps. This is the reason that the claims require crystallization at the time that oxidizing agent is added.

It is maintained that routine optimization (eg. timing of crystallization) does not impart patentability.

Conclusion

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe/
2-15-2010

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626